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Design and Development of Biomedical and Surgical Instruments in Biomedical Applications

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1. Introduction

The breakthrough in biomedical and surgical instrument research follows the advances of newly developed biomedical technologies, improved composite materials, and renovated manufacturing methodologies. These new biomedical and surgical instruments allow physician to perform complex biomedical treatments and surgical operations with better medical quality. Some more complicated biomedical treatments including microsurgery and endoscopic surgery can be performed through precisely controlled biomedical instruments [1]. The newly explored nontoxic, durable and anti-corrosion materials were developed to keep biomedical and surgical instruments from corrosion due to blood contamination and instrumental sterilization. The modern production techniques help to manufacture cost-effective biomedical instruments and newly developed biomedical technology brings improvement on human life quality [2].

Design and development of biomedical instruments combine engineering principle and techniques with biomedical technology to minimize the unsolved gap between engineering and surgery and apply technical design methodology and engineering problem solving skills to improve medical diagnosis, biomedical treatment, and surgical operations [3]. The researches in biomedical and surgical instruments are involved in interdisciplinary fields including biomedical instrument design, biomechanics in mechanical engineering, biomaterials in chemical engineering, and bio-sensing and bioinstrumentation in electrical engineering. The state-of-the-art instrumental development should be documented to procure and trace biomedical instrumental innovation accordingly for continuous improvement. The multi-disciplinary team effort from physicians, engineers, researchers,

and biomedical professionals is required to develop ultimate biomedical product market release accordantly [4]. The crosslink studies of engineering fundamentals, technical disciplines, human anatomy and physiology are preferred in biomedical and surgical instrument design and development. The biomedical and surgical instruments can be applied to many different medical fields, such as organ or tissue probing, occluding, clamping, suturing, ligation, and incising. Since users might not be engineering specialists and improper use of biomedical and surgical instruments can cause alignment problems, the instructed and biomedical protocols should be strictly obeyed and related technical trainings are needed. The biomedical instruments should be kept clean to prevent blood and tissues from hardening since the blood and hardened tissues can be easily trapped in the gap between organ surface and surgical instruments [5]. The patients should be followed up to determine if the biomedical and surgical instruments have been properly used and standard surgical procedures have been applied.

The US biomedical industry is leading worldwide researches in biomedical and surgical instrument development. About 21,000 US companies with over 175,000 employees have been involved in biomedical instrument production [6]. Design and development of biomedical and surgical instruments require advanced techniques implemented to develop special biomedical technology to compete challenging produce market. Since the biomedical and surgical instrument market is high technology oriented, quality competitive and price sensitive, the biomedical and surgical instrument development should be adjusted and controlled for its quality, functionality, manufacturing cost, feasibility, performance, and safety.

There are some common surgical systems in current market. The first surgical system has adjacent surgical preparation and recovery areas [7]. This surgical system has large surgical area with adjacent surgical preparation and recovery areas after operation. The surgical system equipped with biomedical instruments, anesthetic equipment, monitoring equipment, and suture apparatus. The second surgical system has endoscopic biomedical treatment and surgical system [8]. This endoscopic biomedical treatment and surgical system has been supplied to hospitals, nursing homes, and outpatient surgery care centers. This system is widely used in surgical repairing procedures. It also provides computer generated surgical reports to document and track all patient's repairing reports. The third surgical system equips the robotic-assisted biomedical treatment and surgical system [9]. This robotic-assisted biomedical treatment and surgical system can perform remote-controlled biomedical treatment and surgical operation. It consists of the electromechanical instrument with electronic circuit designed as part of computer-controlled sensing system. This robot-controlled biomedical treatment and surgical system can be applied to many complicated patient's medical curing procedures. The fourth surgical system contains biomedical treatment and surgical system for neurosurgical procedure [10]. This neurosurgical system is driven by robotic arm to placing the surgical units. It can quickly hold and place the surgical tools with sensing signal feedback and 3-D endoscope to view and control the biomedical treatment and surgical process.

This chapter focuses on current research, design and development of biomedical instruments in medical treatment and surgical applications by introducing minimally invasive medical treatment and surgical methodology. The newly designed biomedical and surgical instruments can efficiently protect surgical wound during surgery and speed up the operation healing process. The new biomedical and surgical instrument design aids improved body ergonomic design, better driving mechanism, durable functionality, safe performance, and further cost-saving in instrumental production. The computer-aided design, 3-D solid modeling, instrumental motion analysis, and computational simulation have been applied to design and develop these new minimally invasive biomedical and surgical instruments. The computer-aided modeling and simulation results on newly developed biomedical and surgical instruments by using CAD software and structure analysis on instrumental mechanism by applying FEA software are included in this chapter. It can benefit new instrumental design and analysis in geometry, kinematics, dynamics, and visual limitation to assist physician in medical treatment and surgical operation. The experimental testing on prototypes of these newly developed biomedical and surgical instruments have also been included in this chapter to compare with computer-aided design and simulation to verify the credibility of these new biomedical instrument designs.

In general, the connection between new surgical instrument design, CAD and kinematic modeling, simulation and testing, and invasiveness of surgical instrument is as follows: First make conceptual instrument design. Then use CAD software to make 3-D solid modeling and verify kinematic motion by Pro/Mechanism to make sure that all components function properly and there is no part interferences in system assembly. The computer-aided simulation can determine if all systematic functioning parameters are properly defined and selected to provide optimized instrumental performance. The prototype testing is used to verify the instrumental function and compare with results from computer-aided modeling and simulation.

2. Computer-aided design, modeling and simulation

The 3-D solid modeling and simulation on these new biomedical and surgical equipments are based on its designed geometry and volumetric weeping boundary. The kinematics and dynamics of newly designed precision mechanism can be simulated and modeled as an open-loop or closed-loop joint chain with rigid features linked to each other in a series patterns. The kinematical analysis of instrumental structure can provide an analytic methodology to define and simulate the moving mechanism. The 3-D modeling and motion analysis on these multilink systems in kinematical and dynamical simulations allow researchers and professionals performing fundamental study and instrumental conceptual verification in biomedical instrumental design and development stage. The instrumental performance can be improved by systematic design control on kinematical and dynamic parameters. The potential impact of system assembly deviation and production errors can be determined per geometric dimensioning and tolerance (GD&T) analysis. All these instrumental analysis and computer-aided simulation can improve biomedical and surgical

instrument performance to prevent patient's body from being damaging in biomedical treatment and surgical operation. For example, in newly developed surgiclip instruments, the surgiclip distal move can be well controlled to avoid surgiclip dropping from moving channels, operational force to fully close surgiclip is lower than conventional surgical instruments because of new mechanism design, and eliminate the incident of unexpected closure of surgiclip when biomedical instruments are not properly handled by physician. Also the production and manufacturing cost of these newly developed biomedical and surgical instruments can be reduced due to loose dimensional tolerance control on instrumental components because of this new instrumental mechanism design.

2.1. New endo accessible biomedical instrument

Figs. 1 and 2 show the front and rear views of new endoscopic accessible biomedical instrument.

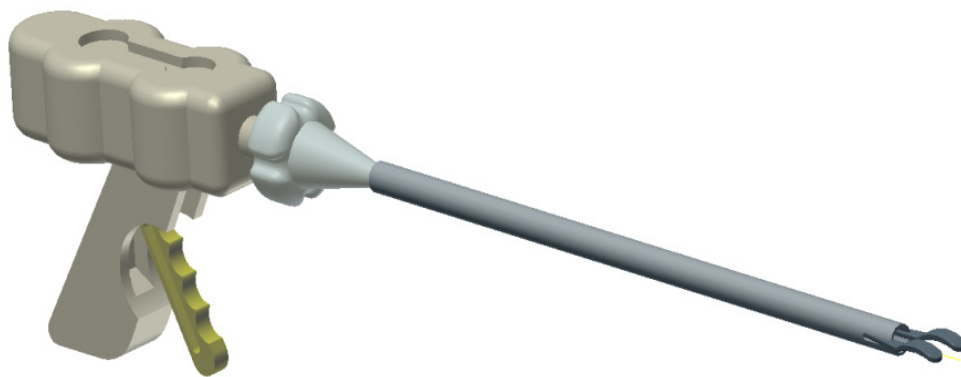


Figure 1. Front view of new endoscopic accessible biomedical instrument



Figure 2. Rear view of new endoscopic accessible biomedical instrument

Fig. 3 displays the internal driving mechanism of this new endoscopic accessible biomedical instrument.

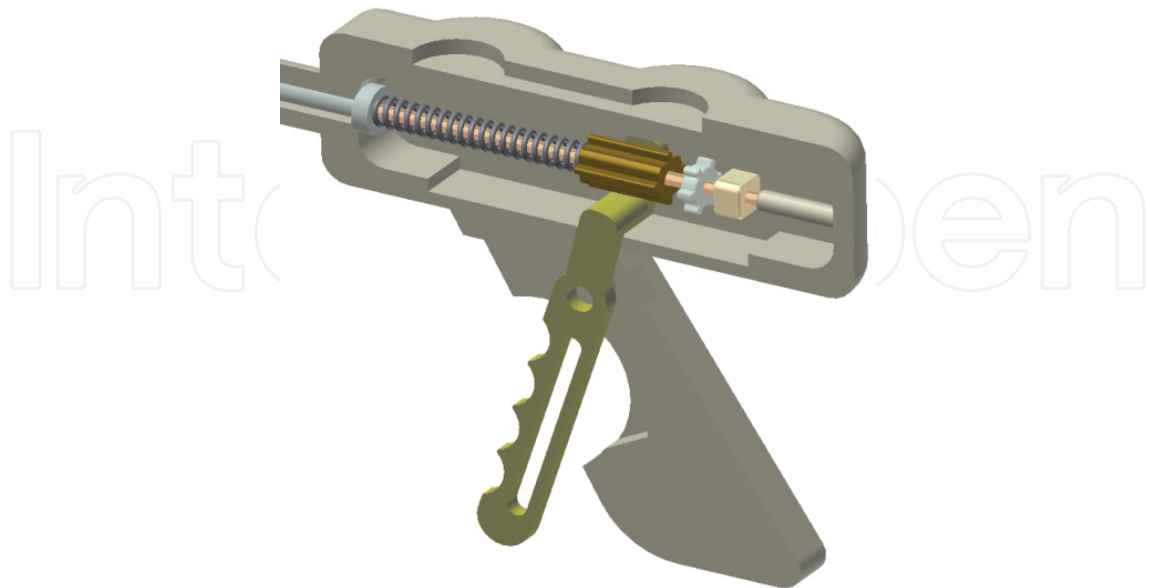


Figure 3. Internal driving mechanism of new endoscopic accessible biomedical instrument

The computer aided kinematic simulation has been performed on this new endoscopic accessible biomedical instrument with result shown in Fig. 4.

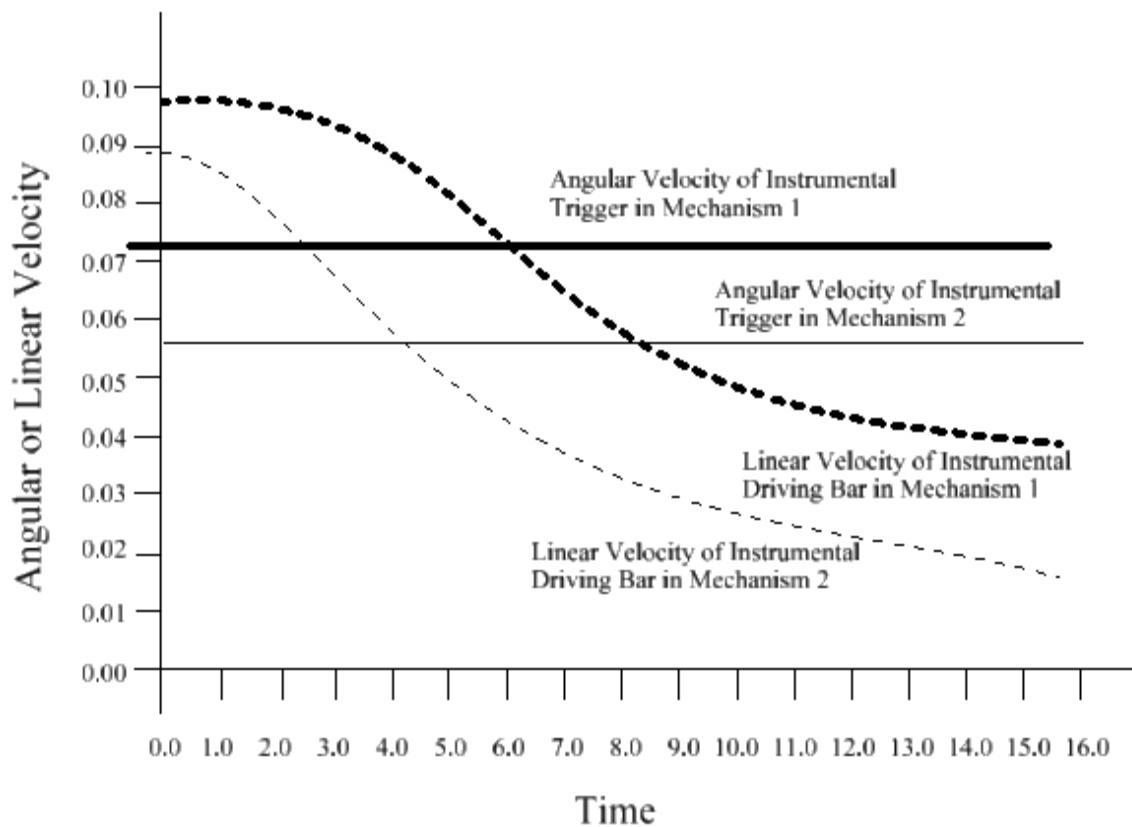


Figure 4. Angular or linear velocity vs. time in endoscopic accessible biomedical instrument

The mechanical advantage (MA) of this new instrument can be determined based on above computational simulation.

$$MA = (VR) * 2.212 = (.04788 / .03732) * 2.212 = 2.838 \tag{1}$$

Here VR is the ratio between linear speed of surgiclip driver and angular speed of instrumental handle and number 2.212 is geometric factor of instrumental driving mechanism depending on internal lever system setup. The above result indicates that, when 20 lbf forces are required to fully close biomedical surgiclip, the physician only need put 3.522 lbf that is less than the normal spec of 4 lbf in surgical operation procedure. This will benefit physician in their medical procedures. The computational simulation of this new endoscopic accessible biomedical instrument is also compared with prototype testing shown in Table 1.

Handle Closure Angle (degree)	Closure Force Measured (lbf)
5	2.455
10	2.646
15	2.875
20	3.184
25	3.318
30	3.535

Table 1. Prototype testing on this new endoscopic biomedical instrument

The force gauge, microscope, and camera measuring system are used to measure the closure force and handle closure angles. In each increment of handle rotation, the required operational force value up to the maximum closure force can be read from force gauge. The prototype testing indicated that the maximum closure force is 3.535 lbf at handle closure angle of 30°. This testing result is very close to the force of 3.522 from computer aided simulation which verifies the feasible functionality of this new endoscopic biomedical instrument. To compare with recently used surgical instruments, this newly developed surgical instrument has several good features: (1). No surgiclip drop-off incident found (2). The operation force is lower than existing instrument (3). Manufacturing cost on this new instrument design might be reduced due to less tolerance control required in components and assembly. Also less closure force is important since it can ease surgical operation and prevent surgeon’s hands from fatigue in daily surgical processes.

2.2. New open accessible biomedical instrument

Figs. 5, 6 and 7 show the front, rear, and front tip views of newly developed open accessible biomedical instrument.

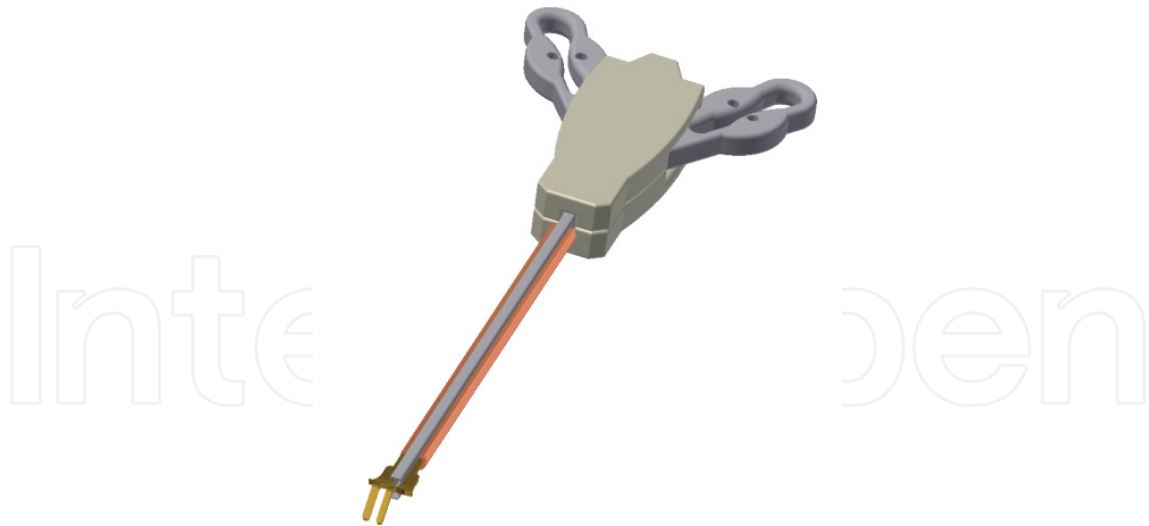


Figure 5. Front view of new open accessible biomedical instrument

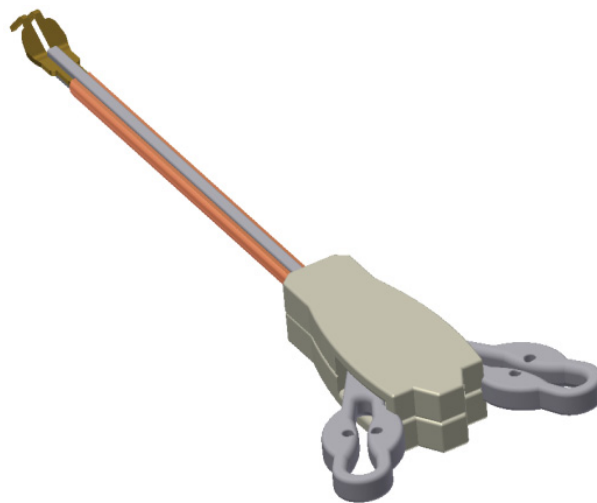


Figure 6. Rear view of new open accessible biomedical instrument

Fig. 8 shows the internal driving mechanism of newly developed open accessible biomedical instrument.

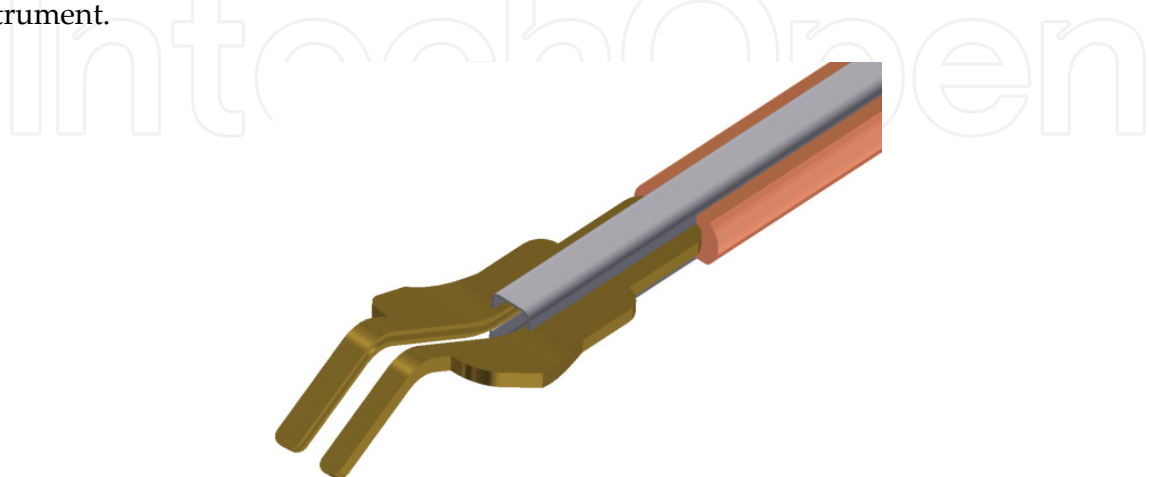


Figure 7. Front tip of new open accessible biomedical instrument

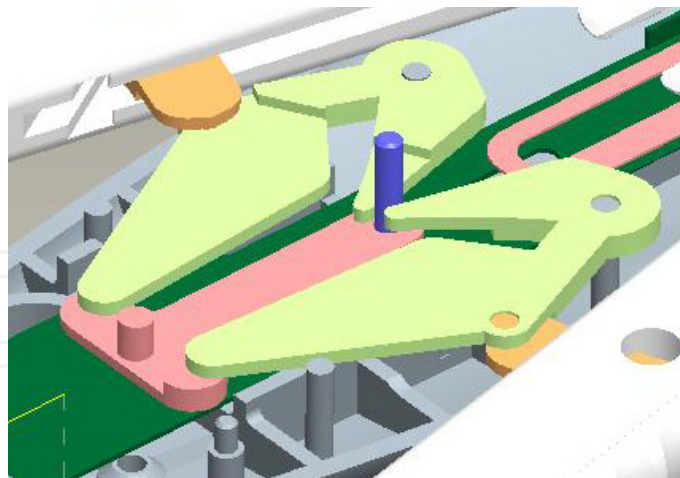


Figure 8. Internal driving mechanism of new open accessible biomedical instrument

The computational modeling and simulation are used to determine kinematic function on driving mechanism in this newly developed open accessible biomedical instrument. The simulation result is presented in Fig. 9.

The results from above computer aided modeling and simulation are used to determine the mechanical advantage (MA) of this new open accessible biomedical instrument.

$$MA = (VR) * 2.245 = (.04812 / .0367) * 2.245 = 2.944 \tag{2}$$

Trigger Rotation Angle (degree)	Operation Force Measured (lbf)
5	2.248
10	2.535
15	2.788
20	3.025
25	3.405

Table 2. Prototype testing on this new open biomedical instrument

Here VR is the ratio between linear speed of surgiclip driver and angular speed of instrumental handle and number 2.245 is geometric factor of instrumental driving mechanism depending on internal lever system setup. Based on above simulated result, the physician only requires applying 3.397 lbf forces if 20 lbf are required to fully form biomedical open surgiclip. Since this force is less than regular spec of 4 lbf in surgical operation procedure, it will ease physician in performing medical procedures. To verify this computational methodology, the prototype testing is performed on this new open accessible biomedical instrument and the tested result is shown in Table 2.

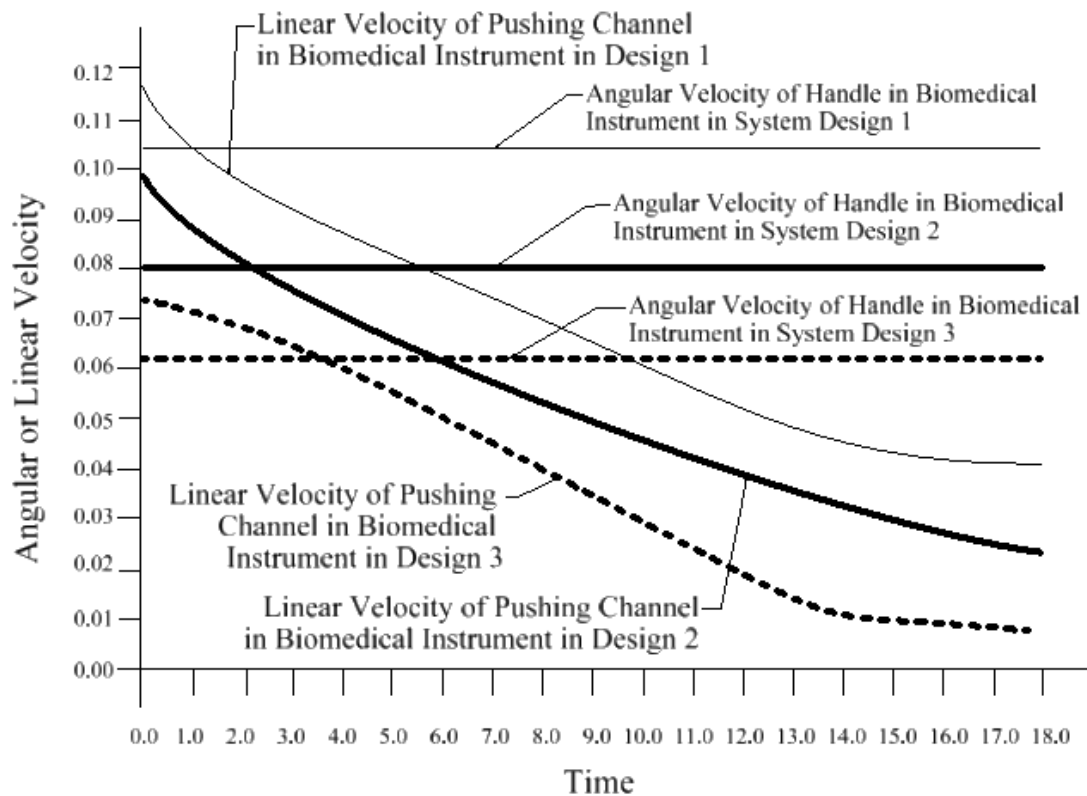


Figure 9. Angular or linear velocity vs. time in open accessible biomedical instrument

The force gauge, microscope, and camera measuring system are used to measure the closure force and handle closure angles. In each increment of handle rotation, the required operational force value up to the maximum closure force can be read from force gauge. The prototype experiment shows that the maximum operation force is 3.405 lbf at trigger rotation angle of 25°. The experiment presents very close result to the 3.397 lbf closure forces obtained from computer aided modeling and simulation. Both results verify the credibility of this new open biomedical instrument design. To compare with recently used surgical instruments, this newly developed surgical instrument has several good features: (1). No surgiclip drop-off incident found (2). The operation force is lower than existing instrument (3). Manufacturing cost on this new instrument design might be reduced due to less tolerance control required in components and assembly. Also less closure force is important since it can ease surgical operation and prevent surgeon's hands from fatigue in daily surgical processes.

3. Conclusion

The design and development of biomedical instrument are introduced in this chapter to benefit readers in learning of fundamental design methodology, biomedical engineering technique, and biomedical instrumental technology. Two new biomedical instruments developed by author are also included for detail explanation in this research field. Both computer aided modeling / simulation and prototype testing demonstrate the reliable function of these two new biomedical instruments with better ergonomic design, no

surgiclip drop-off incident, reduced manufacturing cost, increased mechanical advantage, and improved unit performance. Future improvement will include further simplifying the internal driving mechanism, strengthening the instrumental driving mechanism in case dealing with thick tissues, and continuously performing stress analysis on different instrumental components for optimized design.

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4. References

- [1] Sun, W., Starly, B., Nam, J. & Darling, A., 2005, "Bio-CAD Modeling and Its Application in Computer-Aided Tissue Engineering", *Journal of Computer-Aided Design*, Vol. 37, pp. 1097-1114.
- [2] Barrett, W. & Garber, S., 2003, "Surgical smoke—A review of the literature", *Journal of Surgery Endoscope*, Vol. 17, pp. 979-985.
- [3] Starly, B., Fang, Z., Sun, W. & Regli, W. 2005, "Three-Dimensional Reconstruction for Medical-CAD Modeling", *Journal of Computer-Aided Design and Application*, Vol. 2, pp. 431-438.
- [4] Cheng A., Chiu, P., Chan, P. & Lam, S., 2004, "Endoscopic Hemostasis for Bleeding Gastric Stromal Tumors by Application of Hemoclip", *Journal of Laparoendoscopic & Advanced Surgical techniques*, Vol. 14, pp 69-171.
- [5] Piatt, J., Starly, B., Faerber, E. & Sun, W., 2006, "Application of Computer-Aided Design Methods in Craniofacial Reconstructive Surgery Using Image-Guidance System", *Journal of Neurosurgery*, Vol.104, pp. 64-67.
- [6] Connie, G., Chiu, N., & Nguyen, S., 2011, "Single-incision laparoscopic appendectomy Using conventional instruments: an initial experience using a novel technique", *Journal of Surgical Endoscopy*, Vol. 25, pp. 1153-1159.
- [7] Lin, H., Lo, W., Cheng, Y. & Peng, C., 2007, "Endoscopic Hemoclip Versus Triclip Placement in Patients with High Risk Peptic Ulcer Bleed", *Journal of Gastroenterol*, Vol. 102, pp. 539-543.
- [8] Evans, P., Starly, B. & Sun, W., 2006, "Computer-Aided Tissue Engineering for Design and Evaluation of Lumbar-Spine Arthroplasty", *Journal of Computer-Aided Design and Application*, Vol. 3, pp. 771-778.
- [9] Kassam, A., Thomas, A., Snyderman, C., Carrau, R., Gaedner, P., Mintz, A., & Kanaan, H., 2007, "Fully endoscopic expanded endonasal approach treating skull base lesions in pediatric patients", *Journal of Neurosurgery*, Vol. 106, pp. 75-86.
- [10] Laufer, L., Anand, V. & Schwartz, T., 2007, "Endoscopic, endonasal extended ranssphenoidal, transplanum transtuberculum approach for resection of suprasellar lesions", *Journal of Neurosurgery*, Vol. 106, pp. 400-406.